

III. Remarks

Claims 2-5, 7, 8, and 10-29 are pending in this application, with claim 2 having previously been deemed generic to the elected species. In the outstanding Office action, the Examiner has withdrawn claims 25 and 26 from further consideration, objected to the specification, objected to claim 20 for lack of antecedent basis, rejected claim 12 for lack of enablement, and rejected claims 2, 3, 7, 8, 10-24, and 27-29 for obviousness.

By this paper, Applicants have amended the specification and claim 20 to correct the informalities as identified by the Examiner. Applicants respectfully submit that no new matter has been added by virtue of these amendments.

Reconsideration and further examination of claims 2, 3, 7, 8, and 10-29 are respectfully requested.

THE REJECTION OF CLAIM 12 AS NON-ENABLED

Claim 12 stands rejected under 35 U.S.C. §112(1) for nonenablement, based upon the Examiner's assertion that the specification, while being individually enabling as to the threaded attachment means of the embodiments shown in Figures 1-3 and as to the visualization means of the embodiment shown in Figure 6, "does not reasonably provide enablement for an embodiment combining the threaded attachment means with the visualization means." Applicants respectfully traverse.

Applicants respectfully submit that, after reading Applicants' specification, one of ordinary skill in the art would reasonably be expected to make the recited invention of a visualization tube 22 coupled to upper and lower connectors 1 (as seen in Figure 6) – even if the connectors are threadably attached as shown in Figures 1-3 – because it is simply a matter of package orientation and sequencing that is well within the skill of such a hypothetical person (for example, by threadably-attaching a first connector device 1 in an upper surface of the laminated packaging system 4; coupling the first end of the visualization tube to the first connector and carefully inverting the package so as

to avoid loss a quantity of the composition within the laminated packaging system; threadably-attaching a second connector device to what is now the upper surface of the laminated packaging system; and coupling the second end of the visualization tube to the second connector device).

Accordingly, the withdrawal of this rejection of claim 12 is respectfully requested.

THE OBVIOUSNESS REJECTIONS BASED ON KAWAGUCHI AND KNIERBEIN

Claims 2, 3, 7, 8, 13, and 17-24 and 27-29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over either Candian patent CA 2,432,623 or its U.S. counterpart, pregrant publication US 2004/0104246 (collectively referred to hereinafter as "Kawaguchi," with citations made only to the pre-grant published application for clarity), in view of U.S. Patent No. 6,485,479 ("Knierbein"). Applicants respectfully traverse.

THE KAWAGUCHI REFERENCE

Kawaguchi teaches an adapter for a beverage pack in which a flexible or elastic "fixing member" having a through-hole is first secured to the beverage pack such that the through-hole "is aligned with the opening in the beverage pack" (para. 0010). The pointed "distal end" 12a of a generally tubular adapter 12 is inserted into the beverage pack through both the fixing member's through-hole and the opening, whereupon the elastic fixing member elastically deforms about the adapter to achieve a seal about the adapter:

since the fixing member is liquid-tightly fixes the distal end of the adapter body member in a state of being inserted into the opening in the beverage pack, even if the beverage pack is turned upside down, there will be no leakage of the nutritional beverage or the like contained in the beverage pack from the opening in the beverage pack, or more specifically, from around the adapter body member.

Kawaguchi, para. 0007; see, also, para. 0010 (“When the distal end of the adapter body member is inserted into the beverage pack through the through-hole and the opening, the seal is elastically fitted into the through-hole.”).

Kawaguchi teaches several variations of its tubular adapter, some of which include peripheral features that engage the flexible fixing member over its nominal thickness to achieve an improved seal and prevent unintended pull-out, such as a locking ridge SR as seen in Figure 2, and peripheral threads SS as seen in Figure 4. In each embodiment, though, the adapter body is said to be “formed by injection molding from a semi-hard material such as polypropylene, polyethylene, or another polyolefin, or polycarbonate, polystyrene, or the like” (para. 0029). A further variation of the tubular adapter, shown in Figure 6, includes a flexible, tubular “linking member 114” having a wide radial flange on one end that is secured by an adhesive to the top of the beverage pack, and a narrow radial flange on the other end that cooperates with a rigid, encompassing “annular member” or collar 112b on the adapter body 112 to thereby lock the adapter 110 within the linking member 114.

And Kawaguchi emphasizes that, when attaching the adapter 10, “the pointed end 12a punctures the film 21 [on the beverage pack 20] and goes into the opening 21, but the flange 12c serves as a stopper so that only the pointed end 12a enters the beverage pack 20” (para. 0040) – in other words, the pointed end has punctured the film on the beverage pack well in advance of the engagement of any flange 12c or other peripheral sealing feature, such as the sealing ridge SR or male threads SS, with the fixing member 14 atop the beverage pack. Finally, Kawaguchi teaches only flexible elements secured to the top of the beverage package (the elastic “fixing member 14” shown in Figures 1-5, and the elastic “linking member 114” of Figure 6), and teaches the use of threads only to improve the “elastic fit” achieved between the adapter body and the relatively-thin elastic “fixing member 14.”

THE KNIERBEIN REFERENCE

Knierbein teaches a rigid sterile connector whose lower “coupler 2 with a bottom 3 shaped like a boat” and with “wing-like shoulders 7,8 carry[ing] ribs 9 that taper to a point on the ends of the shoulders 7.8” are welded “to the inside of the bag film of suitable film bags for medicinal liquids” (col. 2, l. 67 to col. 3, l. 8; and col. 4, ll. 54-59). The lower portion of a “channel-like passage 17” defined within the Knierbein connector 1 “is covered and sealed with a puncturable membrane film 18” (col. 3, ll. 58-60), which thus itself forms a portion of the film bag. Upon removal of an integrally-formed “protective cap 5,” an assembly that includes a “plunge pin or spike 19” and a “sleeve nut 20” is screwed onto the upper portion of the Knierbein connector 1, whereupon the plunge pin or spike 19 “punctures” the membrane film 18 (col. 4, ll. 21-23 and 36-38) to thereby extend into the interior of the film bag, while a “continuous edge 23 beneath” the “upper shoulder 22 of the plunge pin 19” is shown and described as being “thus clamped between the tubular top 4 [of the coupler 2] and an inwardly protruding edge 25 of the sleeve nut 20” (as seen in Figures 4 and 5, and described at col. 4, ll. 30-44) to thereby seal the plunge pin’s outer flange (defining continuous edge 23) to the coupler 2.

NO MOTIVATION OR SUGGESTION TO COMBINE KAWAGUCHI AND KNIERBEIN

From the foregoing, Applicants respectfully submit that Kawaguchi and Knierbein are divergent teachings. Specifically, as noted above, Kawaguchi teaches an adapter for a beverage pack whose elastic “fixing member” is first secured to the beverage pack to align its through-hole with the puncturable opening in the beverage pack, whereupon the pointed “distal end” of its generally tubular adapter 12 is inserted into the beverage pack through the fixing member’s through-hole and the beverage pack’s opening, and the elastic fixing member elastically deforms about the adapter to achieve a seal about the adapter’s pointed end 12a. In contrast, as noted above, Knierbein teaches a connector that is actually integrated within the film bag (and itself including a puncturable membrane serving to seal the contents), and the connector is further designed such that the plunge pin’s outer flange sealingly engages the connector’s

upper end (coupler 2). Indeed, Applicants note the Examiner's characterization, at page 5 of the Detailed Action, of Knierbein as teaching that the plunge pin "can be pre-engaged to a container in a sterile manner and hooked up to a patient without rupturing the container" – suggesting that the Examiner himself views Knierbein as teaching that the engagement of the sleeve nut with both the top of the coupler and the plunge pin's outer flange effectively seals the resulting connector assembly even before the plunge pin punctures the membrane 18.

Simply stated, Kawaguchi teaches sealing the tubular adapter proximate to the pierced membrane using the engagement of the flexible fixing/linking member with the tubular adapter, while Knierbein divergently teaches sealing its connector at the remote end of the coupler 2 as the plunge pin's flange is clamped against the coupler's top end (or even, in the Examiner's view, sealing its connector as the sleeve nut threadably engages the top of the coupler). And each is taught within its very different context, of either applying an elastic fixing/linking (and sealing) member to an otherwise fully-contained package (as taught by Kawaguchi), or integrating a connector having its own puncturable (and nonsealing) membrane within the package itself (as taught by Knierbein). And, of course, Kawaguchi teaches the mechanically capturing of the penetrating spike through elastic radial deformation of its fixing/linking member, in further contrast with Knierbein's use of a sleeve nut 20 with which secures its plunge pin 12 within the coupler's channel-like passage 17, and without any elastic radial deformation of any portion of the coupler 2.

In the Office action, the Examiner correctly cites In re Keller, 642 F.2d 413 (CCPA 1981) for the proposition that:

the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

However, as the Court of Appeals for the Federal Circuit later stated in In re Fine, 837 F.2d 1071 (Fed. Cir. 1988), after quoting the very same passage from In re Keller:

But it “cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.” ACS Hosp. Sys., [Inc. v. Montefiore Hosp.], 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed.Cir.1984)], 732 F.2d at 1577, 221 USPQ at 933. And “teachings of references can be combined only if there is some suggestion or incentive to do so.” Id.

See, also, Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed.Cir.1985) (“When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.”). And, more recently, the Court reaffirmed the importance of a suggestion, teaching, or motivation to combine:

the test of whether it would have been obvious to select specific teachings and combine them as did the applicant must still be met by identification of some suggestion, teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the field of the invention.

In re Johnston, 435 F.3d 1381, 1385 (Fed. Cir. 2006).

Still further, the divergent teachings of the references of an applied combination can negate any inference of any suggestion or motivation to combine. See, e.g., Ormco Corp. v. Align Technology, Inc., 463 F.3d 1299, 1308 (Fed. Cir. 2006) (“a reference that ‘teaches away’ from a given combination may negate a motivation to modify the prior art to meet the claimed invention.”); In re Kahn, 441 F.3d 977, 990 (Fed. Cir. 2006) (“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.”).

Given the divergent teachings of Kawaguchi and Knierbein as identified above, Applicants respectfully submit that there is no teaching, suggestion, or motivation to combine the Kawaguchi and Knierbein references in the manner suggested by the Examiner to arrive at the invention recited in claims 2, 3, 7, 8, 13, and 17-24 and 27-29. Applicants also note that neither reference supports the Examiner's hindsight supposition that one of ordinary skill would be motivated to combine Kawaguchi and Knierbein "in order to provide a sterile means of hooking up a patient to the system prior to starting treatment," inasmuch as each reference teaches engaging its penetrating adapter/plunge pin with its fixing member/coupler only when its respective membrane is to be pierced (see, e.g., Kawaguchi at para. 0007; and Knierbein at col. 4, ll. 60-64).

Additionally, Applicants note that, because Kawaguchi teaches gluing its elastic fixing member or elastic linking member to the top of the beverage pack before elastically capturing the adapter body within the fixing member's through-hole or the linking member's axial bore, Kawaguchi likewise fails to teach or suggest a connector having a rim or flange, facing toward the packaging system, on which an adhesive layer has been provided for fixedly attaching the connector device to the packaging system, as recited in independent claim 7, and the applied secondary reference to Knierbein fails to cure this deficiency. Similarly, because Kawaguchi employs a "semi-hard material" for its adapter body when relying upon the elastic fixing member adhered to the top of the beverage pack to cooperatively achieve a seal, Kawaguchi not only fails to teach a pair of axially-spaced rims or flanges as recited in dependent claim 8, wherein the one located nearer the point of the spike is made from a flexible material and the one located farther from the point of the spike is made from a rigid material, but Kawaguchi must necessarily be viewed as teaching away from such a construction. And, once again, the secondary reference to Knierbein likewise fails to cure this deficiency of Kawaguchi. For at least these additional reasons, Applicants respectfully submit that claims 7, 8, 27, and 28 are patentable over the applied combination of Kawaguchi and Knierbein.

In view of the foregoing, the withdrawal of the obviousness rejection of claims 2, 3, 7, 8, 13, and 17-24 and 27-29 is respectfully requested.

THE REFERENCES TO QUINN, SCHAEFER, AND HENDRICKS
DO NOT CURE DEFICIENCIES IN THE UNDERLYING COMBINATION

Claims 14 and 16 stand rejected in the outstanding action under 35 U.S.C. §103(a) as being unpatentable over Kawaguchi and Knierbein “as applied to claims 2, 3, 7, 8, 13, 17-24, and 29 above” and further in view of U.S. Patent No. 4,895,275 (“Quinn”) and U.S. Patent No. 5,993,422 (“Schafer”), while claim 15 stands rejected in the outstanding action under 35 U.S.C. §103(a) as being unpatentable over Kawaguchi and Knierbein “as applied to claims 2, 3, 7, 8, 13, 17-24, and 29 above” and further in view of Quinn and U.S. Patent No. 3,001,525 (“Hendricks”). Applicants respectfully traverse.

While the Examiner is correct in identifying Quinn as using a laminated paper packaging system for enteral administration, Schafer as disclosing use of a pump, and Hendricks as teaching parenteral equipment that includes an intermediate bag for mixing solutions, Quinn, Schafer, and Hendricks, taken either singly or in combination, do not cure the deficiencies of the underlying combination of Kawaguchi and Knierbein as described above with respect to independent claim 2, from which claims 14-16 each indirectly depends (through intervening claim 13). Accordingly, for at least those reasons, Applicants respectfully submit that claims 14-16 are patentable over the art of record in this application.

THE DICKERHOFF REFERENCE DOES NOT CURE DEFICIENCIES
IN THE UNDERLYING COMBINATION

Claims 10-12 stand rejected in the outstanding action under 35 U.S.C. §103(a) as being unpatentable over Kawaguchi and Knierbein “as applied to claims 2, 3, 7, 8, 13, 17-24, and 29 above” and further in view of U.S. Patent No. 4,997,429 (“Dickerhoff”). Applicants respectfully traverse.

As noted in Applicants' previous response, while the Examiner is correct in identifying Dickerhoff as teaching an enteral bottle cap having a vent valve 38 that permits entry of air into the container from which fluid is being drawn, Dickerhoff does nothing to cure the deficiencies of Kawaguchi as described above with respect to independent claim 2, from which claims 10 and 11 each directly depend. Accordingly, for at least those reasons, Applicants respectfully submit that claims 10-12 are patentable over the applied combination of Kawaguchi, Knierbein, and Dickerhoff.

CLAIMS 25 AND 26

As noted above, the Examiner has withdrawn claims 25 and 26 from further consideration "as being drawn to a nonelected invention, there being no allowable generic or linking claim." In view of the foregoing, Applicants respectfully submit that generic claim 2 is allowable over the prior art of record and, hence, reconsideration and examination of claims 25 and 26 is likewise also requested.

CONCLUSION

From the foregoing, Applicants respectfully submit that claims 2, 3, 7, 8, and 10-29 are patentable over the prior art of record in this application; and a notice of allowability with respect to claims 2-5, 7, 8, and 10-29 is courteously solicited.

Respectfully submitted,



Hugo A. Delevie
Reg. No. 32,688

for Dr. Gary M. Lobel
Attorney for Applicants
Reg. No. 51,155

Nestlé HealthCare Nutrition
12 Vreeland Road, Second Floor
P.O. Box 697
Florham Park, NJ 07932-1521
(973) 593-7553

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